Remarks

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application, in light of the following remarks, are respectfully requested. Non-elected claims 14-16, 20-33, 43-45 and 49-69 have been cancelled. Applicants note that the Examiner has withdrawn claim 17 from consideration for purportedly being drawn to a non-elected invention. Claim 17 was included in Group II in the Restriction Requirement dated June 11, 2001. Group II was elected by the applicants in the Response filed September 11, 2001. Therefore, the Examiner should consider claim 17 together with claims 13, 18-19, 34-42, 46-48 and 70. Claims 71-82 have been added. Claims 1-5, 13, 17-19, 34-42, 46-48 and 70 have been amended to remove non-elected subject matter and to clarify the claims. Support for the foregoing amendments and the new claims may be found in the specification, the original claims, the drawings, and the sequence listing, *e.g.*, at the very least at page 19, line 11 through page 21, line 25; page 29, line 7 through page 33, line 2; and page 40, line 7 through page 42, line 13. Following entry of this amendment, claims 1-13, 17-19, 34-42, 46-48, and 70-82 will be pending. No new matter is added by these amendments.

The abstract and title of the invention have been objected to for purportedly not reflecting the claimed invention. By the present amendment, the abstract and title have been amended to reflect the elected invention. Withdrawal of this objection to the specification is respectfully requested. Applicants also respectfully request that the Examiner initial and return the PTO/SB/08A forms submitted with the Information Disclosure Statements filed on January 5, 2001 and August 13, 2001 and filed herewith.

Rejections Under 35 U.S.C. §112, First Paragraph (Written Description)

Claims 1-13, 17-19, 34-42, 46-48 and 70 have been rejected under 35 U.S.C. §112, first paragraph, for purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the

claimed invention at the time the application was filed. Office Action at page 3. Applicants respectfully disagree, and traverse the rejection.

As the Office notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

The Office asserts that all of the nucleic acid molecules encompassed by the claims are not adequately described under 35 U.S.C. § 112. Office Action at page 4. The Office appears to assert that each nucleic acid molecule within the claimed genus must be described by complete structure. These assertions are unfounded. An adequate written description of a genus of nucleic acids may be achieved by means of a "recitation of a representative number of [nucleic acids], defined by nucleotide sequence...or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). The structural feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

Applicants assert that the genus of recombinant DNA constructs is supported by Applicants' disclosure of "structural features common to the members of the genus." In particular, the specification provides descriptions of the components of a recombinant construct, methods of constructing such constructs, and exemplary constructs used to transform cells, at, *e.g.*, page 29 line 7 through page 31 line 14, and page 86 line 17 through page 89 line 9. Applicants have provided a detailed chemical structure for nucleic acid sequences encoding steroid 5α-reductases (*e.g.*, SEQ ID NOs: 2, 4, 6, and 8) and have described the function of, and uses for, these disclosed sequences, *i.e.*, as nucleic acid sequences encoding steroid 5α-reductases. *See, e.g.*, sequence listing and specification at page 19 line 11 through page 21 line 25, page 42 line 19 through page 48 line 29, page 53 line 11 through page 58 line 11, and Examples 2, 7 and 9. Furthermore, the specification sets forth how to isolate nucleic acids encoding steroid 5α-reductases, and how to assay for elevated sterol and stanol levels in transformed plants. *See, e.g.*, page 53 line 11 through page 58 line 11 and Example 3 at pages 101-104.

Moreover, Applicants described representative recombinant DNA constructs in the Examples and elsewhere in the specification. In particular, Example 2 describes the construction of a vector containing a steroid 5α-reductase sequence such as SEQ ID NO: 2, 4, 6 or 8, the *Arabidopsis DET2* gene, or human steroid 5α-reductase. *See, e.g.*, specification at page 100-101. Example 7 also describes the transformation of a plant with a vector to create transgenic plants containing a nucleic acid molecule encoding a steroid 5α-reductase. *See* specification at page 110. *See also* specification at page 86 line 17 through page 98 line 20. Therefore, a person of ordinary skill in the art, *e.g.*, a molecular biologist, would, after reading the present specification, understand that Applicants had possession of the claimed invention.

Accordingly, the present case is clearly different from *Eli Lilly*. The present claims "distinguish the claimed invention from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*.

Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Thus, there is no deficiency in the written description support for the claimed invention.

For the foregoing reasons, Applicants submit that one of ordinary skill in the art would recognize that at the time of filing Applicants were in possession of the claimed inventions. Therefore Applicants respectfully request that the written description rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1-13, 17-19, 34-42, 46-48 and 70 were rejected under 35 U.S.C. §112, first paragraph, because the subject matter allegedly was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicants respectfully disagree, and traverse the rejection. The Office has not met the evidentiary burden to impose an enablement rejection. A specification that discloses how to use a claimed invention "must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original).

The present specification indeed discloses how to make and use the present invention (*e.g.*, by providing protocols for identifying steroid 5α-reductase candidate nucleic acid sequences, and transforming plants with a nucleic acid encoding steroid 5α-reductase). *See, e.g.*, Examples 2, 7 and 9. Moreover, the present specification also discloses additional uses of the claimed invention (*e.g.*, to provide nutritionally enhanced oil compositions, including cholesterol-lowering compositions). *See*, *e.g.*, specification at pages 18-19.

The Office has not provided specific evidence supporting the rejection or any explanation of why the specification allegedly fails to enable these uses. *See In re Wright*, 999 F.2d 1557, 1561-62,

27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement). Therefore, as the specification enables at least the methods of making and using the invention as set forth in the Examples, the enablement requirement has been satisfied. *Cf. Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) ("the enablement requirement is met if the description enables any mode of making and using the invention") (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991).

The Office argues that the claims are not enabled because "the specification does not teach how the DNAs were isolated nor how to isolate other DNAs." Office Action at page 3. Applicants respectfully disagree. As previously discussed, the specification provides a description of the method used to isolate the steroid 5α-reductase sequences, which method can be used to isolate other DNAs. *See, e.g.*, specification at page 53 line 11 through page 58 line 11. With regard to the Office's contention that "Applicant does not teach methods of making transformed plants," Office Action at page 5, Applicants respectfully direct the Office's attention to the extensive description of such methods in the specification, at, *e.g.*, page 89 line 10 through page 98 line 20, Example 7, Example 9, and Example 11. Moreover, it is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

Furthermore, in addition to the examples and specific guidance present in the specification, there are considerable resources available to one of skill in the art regarding conditions and approaches that can be utilized to isolate, confirm, and introduce into other hosts nucleic acid sequences within the scope of the claims. *See, e.g.*, references cited in the specification at pages 87 and 94. Furthermore, the level of skill in this art is high, and the performance of routine and well-known steps, such as, *e.g.*, an assay to confirm elevated sitostanol levels, cannot create undue

experimentation even if it is laborious. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The Office Action suggests that the present application allegedly lacks enablement because "[d]etermining which, if any steroid 5α-reductase DNA sequences result in overproduction of sterols and tocopherols would require screening a myriad of constructs...and plants transformed therewith." Office Action at page 6. To the extent that the Office Action suggests there is a requirement for *a priori* predictability without recourse to any experimentation, that position is without legal support. *Cf. Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984) ("[t]hat some experimentation is necessary does not preclude enablement"). The proper test of enablement in such a situation is whether the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." *See In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991).

The Office Action's "test" for enablement would require an art worker to be able, without even entering a laboratory, to name particular transgenic plants that have increased levels of sterols and/or stanols. However, that is not the *Vaeck* test. Under the *Vaeck* test, the specification is enabling if it "adequately guide[s] the art worker to determine, without undue experimentation, which [particular transgenic plants] among all those encompassed by the [group of plants transformed with steroid 5α-reductase DNA sequences] possess [increased levels of sterols and/or stanols]." *In re Vaeck*, 947 F.2d at 496, 20 U.S.P.Q.2d at 1445. The *Vaeck* test recognizes proper enablement where the skilled art worker is able to determine, once a particular transgenic plant has been selected from the group and based on a reasonable experiment, whether that particular plant has increased levels of sterols and/or stanols.

The high level of skill in the art, the extensive knowledge available to one of skill in the art, and the teachings of the present specification adequately guide the art worker to determine, after

selection and without undue experimentation, which nucleic acid molecules encompassed by the claims possess the disclosed utilities. Performing routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-19 (C.C.P.A. 1976).

The Office Action expresses concern that "testing of the putative positives would entail screening through a host of false positives." Office Action at pages 6-7. This concern is irrelevant. "It is not a function of the claims to specifically exclude...possible inoperative substances." *Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984) (citing *In re Dinh-Nguyen*, 492 F.2d 856, 858-59, 181 U.S.P.Q 46, 48 (C.C.P.A. 1974)). The case law does not require "each and every compound within a claim to be equally useful for each and every contemplated application." *Ex Parte Cole*, 223 U.S.P.Q. 94, 95 (B.P.A.I. 1983).

There is no legal requirement that each and every steroid 5α-reductase be useful for each and every contemplated utility. What is required is that the art worker know how to determine, after reasonable experimentation, whether a particular steroid 5α-reductase selected from the group is useful for a particular utility. The Office Action has not contended, nor can it contend that this is unachievable with the nucleic acid molecules of the present claims. Instead, an improper test has been manufactured and applied which requires (without legal authority) demonstration of *a priori* knowledge of whether a particular molecule within the claimed genus would work.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the enablement rejections under 35 U.S.C. §112, first paragraph.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 2-6, 17-19, 34-35, 38-42, 46-48 and 70 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly "failing to particularly point out and distinctly claim the

subject matter which applicant regards as the invention." Office Action at page 7. Applicants respectfully disagree, and traverse the rejections.

Rejection of claims 2-4

In the Office Action, claims 2-4 were rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for using the phrase "which, when said promoter is a seed specific promoter." Office Action at page 7. Applicants respectfully disagree. However, to facilitate prosecution, Applicants have modified the phrase to read "wherein said promoter is a seed specific promoter" in the claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of claim 5

Claim 5 was rejected as comprising improper Markush language, and as allegedly indefinite under 35 U.S.C. § 112, second paragraph for using the phrase "consisting of a site derived." Office Action at page 7. Applicants respectfully disagree. However, to facilitate prosecution, Applicants have amended the claim, and respectfully request reconsideration and withdrawal of the rejection.

Rejection of claims 17-19, 34-25, 38-40, 46-48 and 70

Claims 17-19, 34-25, 38-40, 46-48 and 70 were rejected under 35 U.S.C. § 112, second paragraph as indefinite because they are dependent on non-elected claims. Office Action at page 7. Applicants have amended the claims to remove the dependencies on non-elected claims. Applicants respectfully submit that this rejection is rendered moot by the foregoing amendment. In light of the amended claims, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection of claims 38 and 39

Claims 38 and 39 were rejected under 35 U.S.C. § 112, second paragraph as indefinite due to typographical errors in the claims, *e.g.*, "conductive" instead of "conducive." Office Action at pages 7-8. The claims have been amended to correct the typographical errors, and Applicants submit that this rejection is rendered moot by the foregoing amendment. In light of the amended claims, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection of claim 42

Claim 42 was rejected as comprising improper Markush language. Office Action at page 8. Applicants respectfully disagree. However, to facilitate prosecution, Applicants have amended the claim, and respectfully request reconsideration and withdrawal of the rejection.

Rejection of claims 46-48

Claims 46-48 were rejected under 35 U.S.C. § 112, second paragraph as indefinite because the phrase "said enzyme encoding DNAs" lacks antecedent basis, and because the phrase "when said regulatory signals cause seed specific expression" allegedly does not further limit the claims. Office Action at page 8. Applicants respectfully disagree. However, to facilitate prosecution, Applicants have amended the claims to recite "wherein said regulatory signals cause seed specific expression" and have amended the references to DNA to accord with amended base claim 42. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejections Under 35 U.S.C. § 101

Claims 34, 35, 37, and 41 were rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter because the claims allegedly encompass untransformed plants and seed. Applicants respectfully disagree. However, to facilitate prosecution, Applicants have amended claims 34, 35, 37, and 41 to clarify that the claimed plants, seed, and progeny comprise the introduced DNA of ultimate base claim 13. Applicants submit that this rejection is rendered moot by the foregoing amendment. In light of the amended claims, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection Under 35 U.S.C. § 102(b) and 35 U.S.C. § 103

Claims 1 and 7-12 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Li *et al.* (*Proc. Natl. Acad. Sci.* 34:3555-3559 (1997)) (hereinafter "Li"). The Examiner contends

that Li anticipates claims 1 and 7-12. Office Action at page 9. Applicants respectfully disagree, and traverse the rejection.

For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988). It is well-established law that an anticipatory reference "must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it" and "must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure." *In re Spada*, 911 F.2d 705, 708, 15 U.S.P.Q.2d 1655, 1657 (Fed. Cir. 1990); *Chester v. Miller*, 906 F.2d 1574 (Fed. Cir. 1990). Enablement requires that "those in the art [can] make and use the invention without 'undue experimentation.'" *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Li is not an anticipatory reference because it fails to describe a steroid 5α-reductase nucleic acid sequence. The Federal Circuit has held that a nucleic acid is not defined or described by its name (*e.g.*, a cDNA encoding insulin), but "requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 42 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Because Li does not teach any nucleic acid sequences, it cannot anticipate the present claims directed to steroid 5α-reductase sequences. Moreover, Li also fails to teach a seed-specific promoter or a plastid-specific promoter. The Examiner has not provided evidence that Li would allow one of ordinary skill in the art to arrive at the present invention without undue experimentation.

Because Li does not teach all of the elements of claims 1 and 7-12, Applicants submit that Li does not anticipate the claims. For the above-stated reasons, Applicants respectfully request that the Section 102(b) rejections be withdrawn.

Claims 1 and 3-12 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over Li in view of Maliga *et al.* (U.S. Patent No. 5,530,191) (hereinafter "Maliga"). Office Action at pages 9-10. Applicants respectfully traverse this rejection.

The Federal Circuit has held that a proper analysis under Section 103 requires a consideration of "whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process." *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). In the present case, there is no art-based suggestion to combine the teachings of these different references, and their combination is improper. Contrary to the Examiner's assertions, Maliga does not teach or even suggest the general desirability of plastid-based expression, or that "plastid transformation allows for combination of characteristics that are either difficult or impossible to combine." Office Action at page 10. Whatever else Maliga teaches or suggests, it does not teach or even suggest the combination of a plasmid-specific promoter and a sequence encoding a steroid 5α-reductase nucleic acid sequence.

Even if there were such a suggestion, however, Maliga does not supply that which Li lacks. The failure of the Li disclosure to describe a steroid 5α-reductase nucleic acid sequence and enable its uses as required by the present claims is not overcome by the disclosure of Maliga. The Examiner has argued that Maliga teaches "plastid transformation/expression cassette elements", but these features do not remedy Li's lack of a sufficient disclosure of a steroid 5α-reductase nucleic acid sequence. Hence, the cited references taken alone or in combination do not teach, suggest, or make obvious the present invention.

Claims 1-2 and 7-12 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over Li in view of Falco *et al.* (Abstract of Bio-Technology 13(6):577-582 (1995)) (hereinafter "Falco"). Office Action at pages 10-11. Applicants respectfully traverse this rejection.

The Federal Circuit has held that a proper analysis under Section 103 requires a consideration of "whether the prior art would have suggested to those of ordinary skill in the art that

they should make the claimed composition or device, or carry out the claimed process." *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). In the present case, there is no art-based suggestion to combine the teachings of these different references, and their combination is improper. Contrary to the Examiner's assertions, Falco does not teach or suggest the general usefulness of seed metabolism modification. Office Action at page 11. No teaching or suggestion is made in Falco to replace the specific enzymes disclosed with other enzymes such as the presently claimed steroid 5α-reductase.

Even if there were such a suggestion, however, Falco does not supply that which Li lacks. The failure of the Li disclosure to describe a steroid 5α-reductase nucleic acid sequence and enable its uses as required by the present claims is not overcome by the disclosure of Falco. The Examiner has argued that Falco teaches a "seed specific promoter and transit peptide", but these features do not remedy Li's lack of a sufficient disclosure of a steroid 5α-reductase nucleic acid sequence. Hence, the cited references taken alone or in combination do not teach, suggest, or make obvious the present invention.

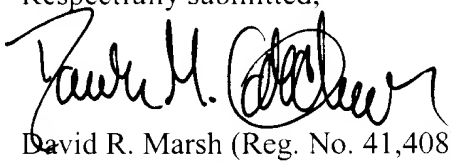
For the above-stated reasons, Applicants respectfully request that the rejections under 35 U.S.C. § 103 be withdrawn.

Conclusion

In view of the foregoing arguments and amendments, each of the presently pending claims is believed to be in immediate condition for allowance. All of the stated grounds of rejection have been traversed, accommodated, or rendered moot. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is encouraged to contact the undersigned at 202.942.5071 should any additional information be necessary for allowance.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387, referencing matter number 16516.152.

Respectfully submitted,



David R. Marsh (Reg. No. 41,408)
June E. Cohan (Reg. No. 43,741)
Dawn M. Gardner (Reg. No. 44,118)

Date: November 21, 2002

ARNOLD & PORTER
555 Twelfth Street, NW
Washington, D.C. 20004
(202) 942-5000 telephone
(202) 942-5999 facsimile

Marked Up Versions

IN THE TITLE:

VECTORS, TRANSFORMED CELLS AND TRANSGENIC PLANTS **COMPRISING A STEROID REDUCTASE DNA** [CONTAINING ALTERED LEVELS OF STEROL COMPOUNDS AND TOCOPHEROLS]

IN THE SPECIFICATION:

On page 157:

Abstract of the **Invention** [Disclosure]

Provided are recombinant constructs comprising DNA sequences encoding **steroid 5α-reductase** enzymes effective in altering the biosynthesis and accumulation of sterol compounds and tocopherols in transgenic plants. Also provided are methods of using such constructs to produce transgenic plants, seeds of which contain elevated levels of sitostanol and/or sitostanol esters, and α-tocopherol, as well as reduced levels of campesterol and campestanol and their corresponding esters. These seeds also contain the novel sterol brassicastanol. Oil obtained from seeds of such transgenic plants is also provided. This oil can be used to prepare food and pharmaceutical compositions effective in lowering the level of low density lipoprotein cholesterol in blood serum. In addition, novel DNA sequences encoding plant steroid 5α-reductases are also disclosed.

IN THE CLAIMS:

1. (Amended) A recombinant construct, comprising as operably linked components in the 5' to 3' direction, [a member selected from the group consisting of:

a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a 3-hydroxysteroid oxidase enzyme, and a transcription termination signal sequence;]

a seed specific promoter or a plastid specific promoter [functional in a plant plastid], a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence[;

a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, and a transcription termination signal sequence;

a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a sterol methyl transferase enzyme, and a transcription termination signal sequence;

a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a sterol acyltransferase enzyme, and a transcription termination signal sequence; and

a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a S-adenosylmethionine-dependent γ-tocopherol methyltransferase enzyme, and a transcription termination signal sequence].

2. (Amended) The recombinant construct of claim 1, [which, when] wherein said promoter is a seed-specific promoter[,] and wherein said recombinant construct further comprises a transit peptide coding region capable of directing transport of said enzyme into a plastid, operatively linked to said DNA sequence.

3. (Amended) The recombinant construct of claim 1, [which, when] wherein said promoter is a plastid specific promoter [functional in a plant plastid,] and said recombinant construct further comprises:

a gene encoding a selectable marker for selection of plant cells comprising a plastid expressing said selectable marker, and

DNA regions of homology to the genome of said plastid, wherein said DNA regions of homology flank said plastid specific promoter [functional in a plant plastid], said DNA sequence, said transcription termination signal sequence, and said gene encoding a selectable marker.

4. (Amended) The recombinant construct of claim 1, [which, when] wherein said promoter is a plastid specific promoter [functional in a plant plastid,] and said recombinant construct further comprises a ribosome binding site joined to said [plastid] promoter.

5. (Amended) The recombinant construct of claim 4, wherein said ribosome binding site is [obtainable] obtained from a leader sequence selected from the group consisting of [a site derived from] a plastid leader sequence, a bacterial leader sequence, [or] and a bacteriophage leader sequence.

7. (Amended.) A recombinant vector comprising [the] a recombinant construct [of claim 1], comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a plastid specific promoter, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence.

9. (Amended) A transformed host cell comprising [the] a recombinant construct [of claim 1], comprising as operably linked components in the 5' to 3' direction, a seed specific

promoter or a plastid specific promoter, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence.

11. (Amended) A plant comprising at least one transformed host plant cell [of claim 10] comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a plastid specific promoter, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence.

12. (Amended) A seed comprising at least one transformed host plant cell [of claim 10] comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a plastid specific promoter, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence.

13. (Amended) A plant, the genome of which comprises introduced [DNA selected from the group consisting of:

DNA encoding a 3-hydroxysteroid oxidase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA;]

DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA[;

DNAs encoding a 3-hydroxysteroid oxidase enzyme and a steroid 5α-reductase enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs;

DNAs encoding a 3-hydroxysteroid oxidase enzyme and a tocopherol biosynthetic enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, and at least one tocopherol compound, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs;

DNAs encoding a steroid 5α-reductase enzyme and a tocopherol biosynthetic enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, and at least one tocopherol compound, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs;

DNAs encoding a 3-hydroxysteroid oxidase enzyme, a steroid 5α-reductase enzyme and a tocopherol biosynthetic enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, and at least one tocopherol compound, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs;

DNA encoding a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-

specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of at least one sterol, at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, or mixtures thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA;

DNAs encoding a 3-hydroxysteroid oxidase enzyme and a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of at least one sterol, at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, or mixtures thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs;

DNAs encoding a steroid 5α-reductase enzyme and a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of at least one sterol, at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, or mixtures thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs;

DNAs encoding a 3-hydroxysteroid oxidase enzyme, a steroid 5α-reductase enzyme and a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of at least one sterol, at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, or mixtures thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs;

DNAs encoding a 3-hydroxysteroid oxidase enzyme, a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, and a sterol methyltransferase enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of at least one sterol, at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, or mixtures thereof, as well as a reduced level of campesterol, a campesterol ester, campestanol, a campestanol ester, or mixtures thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs;

DNAs encoding a steroid 5α-reductase enzyme, a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, and a sterol methyltransferase enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of at least one sterol, at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, or mixtures thereof, as well as a reduced level of campesterol, a campesterol ester, campestanol, a campestanol ester, or mixtures thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs; and

DNAs encoding a 3-hydroxysteroid oxidase enzyme, a steroid 5α-reductase enzyme, a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, and a sterol methyltransferase enzyme, wherein said introduced DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNAs, and wherein seeds of said plant contain an elevated level of at least one sterol, at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, or mixtures thereof, as well as a reduced level of campesterol, a campesterol ester, campestanol, a campestanol ester, or mixtures thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNAs].

17. (Amended) The plant of claim 13[, 14, 15 or 16], wherein the seed of said plant contains at least one of brassicastanol, brassicastanol ester, stigmastanol or stigmastanol ester.

18. (Amended) The plant of claim 13[, 14, 15 or 16], wherein said regulatory signals cause seed-specific expression of said introduced DNA[s], and wherein [each of] said introduced DNA[s] is further operatively linked to a transit peptide coding region capable of directing transport of said enzyme encoded thereby into a plastid.

19. (Amended) The plant of claim 13[, 14, 15 or 16], wherein said regulatory signals cause plastid-specific expression of said introduced DNA[s], and wherein said genome is a plastid genome.

34. (Amended) A seed of a plant [according to claim 13, 20, 24 or 26], the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA., wherein said seed comprises said introduced DNA.

35. (Amended) Progeny of a plant [according to claim 13, 20, 24 or 26], the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of

sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, wherein said progeny comprises said introduced DNA.

36. (Amended) A method of producing a plant that accumulates an elevated level of a compound selected from the group consisting of sitosterol, at least one sitosterol ester, sitostanol, at least one sitostanol ester, and mixtures thereof, in seed of said plant compared to seed of a corresponding plant comprising no introduced DNA encoding a peptide, polypeptide, or protein that affects the biosynthesis and accumulation of a phytosterol or phytosterol ester, or a phytostanol or phytostanol ester, comprising sexually crossing a plant [of claim 13, 20, 24 or 26], the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, with said corresponding plant.

37. (Amended) A plant produced by the method of claim 36, wherein said plant comprises said introduced DNA.

38. (Amended) A method of producing oil containing sitostanol or a sitostanol ester, comprising culturing cells from a plant [of claim 13, 20, 24 or 26], the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one

sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, for a time and under conditions [conductive] conducive to the production of oil [contain] containing sitostanol or sitostanol ester, and recovering said oil containing sitostanol or a sitostanol ester produced thereby.

39. (Amended) A method for producing a sitostanol or a sitostanol ester comprising culturing cells from a plant [of claim 13, 20, 24 or 26], the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, for a time and under conditions [conductive] conducive to the production of sitostanol or a sitostanol ester, and recovering said sitostanol or sitostanol ester produced thereby.

40. (Amended) A plant [of claim 13, 20, 24 or 26], the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, wherein said plant is an [apomicitic] apomictic plant.

41. (Amended) A seed resulting from a cross of [the] a plant [of claim 40], the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said

introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, wherein said plant is an apomictic plant, with a nurse cultivar, wherein said seed comprises said introduced DNA.

42. (Amended) A method of producing a compound selected from the group consisting of at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, and mixtures thereof, in a seed, comprising obtaining a transformed plant that produces said seed, wherein said plant has and expresses in its genome [DNA selected from the group consisting of:

DNA encoding a 3-hydroxysteroid oxidase enzyme, wherein said DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNA;]

DNA encoding a steroid 5α-reductase enzyme, wherein said DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNA,[;

DNAs encoding a 3-hydroxysteroid oxidase enzyme and a steroid 5α-reductase enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNAs;

DNAs encoding a 3-hydroxysteroid oxidase enzyme and a tocopherol biosynthetic enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNAs;

DNAs encoding a steroid 5α-reductase enzyme, and a tocopherol biosynthetic enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNAs;

DNAs encoding a 3-hydroxysteroid oxidase enzyme, a steroid 5α-reductase enzyme, and a tocopherol biosynthetic enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNAs;

DNA encoding a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, wherein said DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNA;

DNAs encoding a 3-hydroxysteroid oxidase enzyme and a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNAs;

DNAs encoding a steroid 5α-reductase enzyme and a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNAs;

DNAs encoding a 3-hydroxysteroid oxidase enzyme, a steroid 5α-reductase enzyme, and a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of DNAs;

DNAs encoding a 3-hydroxysteroid oxidase enzyme, a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, and a sterol methyltransferase enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNAs;

DNAs encoding a steroid 5α-reductase enzyme, a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, and a sterol methyltransferase enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNAs; and

DNAs encoding a 3-hydroxysteroid oxidase enzyme, a steroid 5α-reductase enzyme, a 3-hydroxy-3-methylglutaryl-CoA reductase enzyme, and a sterol methyltransferase enzyme, wherein said DNAs are operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNAs;] and

recovering said compound from said seed [at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, or mixtures thereof].

46. (Amended) The method of claim 42, [43, 44 or 45,] wherein [when] said regulatory signals cause seed-specific expression of said [enzyme-encoding] DNA[s], and wherein [each of] said [enzyme-encoding] DNA[s] is further operatively linked to a transit peptide coding region capable of directing transport of said steroid 5α-reductase enzyme [encoded thereby] into a plastid.

47. (Amended) The method of claim 42, [43, 44 or 45] wherein[, when] said regulatory signals cause seed-specific expression of said [enzyme-encoding] DNA[s], and wherein said genome is the nuclear genome.

48. (Amended) The method of claim 42, [43, 44 or 45] wherein[,when] said regulatory signals cause plastid-specific expression of said [enzyme-encoding] DNA[s], and wherein said genome is a plastid genome.

70. (Amended) A uniform population of plants according to claim 13[, 20, 24 or 26].

Clean Copy of Pending Claims

1. (Amended) A recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a plastid specific promoter, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence.

2. (Amended) The recombinant construct of claim 1, wherein said promoter is a seed-specific promoter and wherein said recombinant construct further comprises a transit peptide coding region capable of directing transport of said enzyme into a plastid, operatively linked to said DNA sequence.

3. (Amended) The recombinant construct of claim 1, wherein said promoter is a plastid specific promoter and said recombinant construct further comprises:

a gene encoding a selectable marker for selection of plant cells comprising a plastid expressing said selectable marker, and

DNA regions of homology to the genome of said plastid, wherein said DNA regions of homology flank said plastid specific promoter, said DNA sequence, said transcription termination signal sequence, and said gene encoding a selectable marker.

4. (Amended) The recombinant construct of claim 1, wherein said promoter is a plastid specific promoter and said recombinant construct further comprises a ribosome binding site joined to said promoter.

5. (Amended) The recombinant construct of claim 4, wherein said ribosome binding site is obtained from a leader sequence selected from the group consisting of a plastid leader sequence, a bacterial leader sequence, and a bacteriophage leader sequence.

6. (Reiterated) The recombinant construct of claim 5, wherein said ribosome binding site is selected from the group consisting of the binding site of the gene 10 leader and the rbcLRBS site.

7. (Amended) A recombinant vector comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a plastid specific promoter, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence.

8. (Reiterated) The recombinant vector of claim 7, wherein said vector is a plant expression vector.

9. (Amended) A transformed host cell comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a plastid specific promoter, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence.

10. (Reiterated) The transformed host cell of claim 9, wherein said host cell is a plant cell.

11. (Amended) A plant comprising at least one transformed host plant cell comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a plastid specific promoter, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence.

12. (Amended) A seed comprising at least one transformed host plant cell comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a plastid specific promoter, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence.

13. (Amended) A plant, the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA.

17. (Amended) The plant of claim 13, wherein the seed of said plant contains at least one of brassicastanol, brassicastanol ester, stigmastanol or stigmastanol ester.

18. (Amended) The plant of claim 13, wherein said regulatory signals cause seed-specific expression of said introduced DNA, and wherein said introduced DNA is further operatively linked to a transit peptide coding region capable of directing transport of said enzyme encoded thereby into a plastid.

19. (Amended) The plant of claim 13, wherein said regulatory signals cause plastid-specific expression of said introduced DNA, and wherein said genome is a plastid genome.

34. (Amended) A seed of a plant, the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to

regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, wherein said seed comprises said introduced DNA.

35. (Amended) Progeny of a plant, the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, wherein said progeny comprises said introduced DNA.

36. (Amended) A method of producing a plant that accumulates an elevated level of a compound selected from the group consisting of sitosterol, at least one sitosterol ester, sitostanol, at least one sitostanol ester, and mixtures thereof, in seed of said plant compared to seed of a corresponding plant comprising no introduced DNA encoding a peptide, polypeptide, or protein that affects the biosynthesis and accumulation of a phytosterol or phytosterol ester, or a phytostanol or phytostanol ester, comprising sexually crossing a plant, the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, with said corresponding plant.

37. (Amended) A plant produced by the method of claim 36, wherein said plant comprises said introduced DNA.

38. (Amended) A method of producing oil containing sitostanol or a sitostanol ester, comprising culturing cells from a plant, the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, for a time and under conditions conducive to the production of oil containing sitostanol or sitostanol ester, and recovering said oil containing sitostanol or a sitostanol ester produced thereby.

39. (Amended) A method for producing a sitostanol or a sitostanol ester comprising culturing cells from a plant, the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, for a time and under conditions conducive to the production of sitostanol or a sitostanol ester, and recovering said sitostanol or sitostanol ester produced thereby.

40. (Amended) A plant, the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein

seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, wherein said plant is an apomictic plant.

41. (Amended) A seed resulting from a cross of a plant, the genome of which comprises introduced DNA encoding a steroid 5α-reductase enzyme, wherein said introduced DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said introduced DNA, and wherein seeds of said plant contain an elevated level of sitostanol, at least one sitostanol ester, or a mixture thereof, compared to seeds of an otherwise identical plant, the genome of which does not comprise said introduced DNA, wherein said plant is an apomictic plant, with a nurse cultivar, wherein said seed comprises said introduced DNA.

42. (Amended) A method of producing a compound selected from the group consisting of at least one phytosterol, at least one phytosterol ester, at least one phytostanol, at least one phytostanol ester, and mixtures thereof, in a seed, comprising obtaining a transformed plant that produces said seed, wherein said plant has and expresses in its genome DNA encoding a steroid 5α-reductase enzyme, wherein said DNA is operatively linked to regulatory signals that cause seed-specific or plastid-specific expression of said DNA, and recovering said compound from said seed.

46. (Amended) The method of claim 42, wherein said regulatory signals cause seed-specific expression of said DNA, and wherein said DNA is further operatively linked to a transit peptide coding region capable of directing transport of said steroid 5α-reductase enzyme into a plastid.

47. (Amended) The method of claim 42, wherein said regulatory signals cause seed-specific expression of said DNA, and wherein said genome is the nuclear genome.

48. (Amended) The method of claim 42, wherein said regulatory signals cause plastid-specific expression of said DNA, and wherein said genome is a plastid genome.

70. (Amended) A uniform population of plants according to claim 13.

71. (New) A recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence, wherein said DNA sequence is selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, complements thereof, and degenerate sequences thereof.

72. (New) The recombinant construct of claim 71, wherein said promoter is a seed-specific promoter and wherein said recombinant construct further comprises a transit peptide coding region capable of directing transport of said enzyme into a plastid, operatively linked to said DNA sequence.

73. (New) The recombinant construct of claim 71, wherein said promoter is a promoter functional in a plant plastid and said recombinant construct further comprises:

a gene encoding a selectable marker for selection of plant cells comprising a plastid expressing said selectable marker, and

DNA regions of homology to the genome of said plastid, wherein said DNA regions of homology flank said promoter functional in a plant plastid, said DNA sequence, said transcription termination signal sequence, and said gene encoding a selectable marker.

74. (New) The recombinant construct of claim 71, wherein said promoter is a promoter functional in a plant plastid and said recombinant construct further comprises a ribosome binding site joined to said promoter.

75. (New) The recombinant construct of claim 74, wherein said ribosome binding site is obtained from a leader sequence selected from the group consisting of a plastid leader sequence, a bacterial leader sequence, and a bacteriophage leader sequence.

76. (New) The recombinant construct of claim 75, wherein said ribosome binding site is selected from the group consisting of the binding site of the gene 10 leader and the rbcLRBS site.

77. (New) A recombinant vector comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence, wherein said DNA sequence is selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, complements thereof, and degenerate sequences thereof.

78. (New) The recombinant vector of claim 77, wherein said vector is a plant expression vector.

79. (New) A transformed host cell comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence, wherein said DNA sequence is selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, complements thereof, and degenerate sequences thereof.

80. (New) The transformed host cell of claim 79, wherein said host cell is a plant cell.

81. (New) A plant comprising at least one transformed host plant cell comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence, wherein said DNA sequence is selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, complements thereof, and degenerate sequences thereof.

82. (New) A seed comprising at least one transformed host plant cell comprising a recombinant construct, comprising as operably linked components in the 5' to 3' direction, a seed specific promoter or a promoter functional in a plant plastid, a DNA sequence encoding a steroid 5α-reductase enzyme, and a transcription termination signal sequence, wherein said DNA sequence is selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, complements thereof, and degenerate sequences thereof.